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Original Article

FORMULATION AND EVALUATION OF SUSTAINED-RELEASE TABLETS OF TENELIGLIPTIN BY USING THE LIQUID-SOLID COMPACTION METHOD

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ABSTRACT

Background: *The liquid solid technique is an innovative approach aimed at enhancing the solubility and bioavailability of poorly water-soluble drugs, particularly those classified as BCS Class II. This technique is crucial in the formulation of sustained-release (SR) tablets, which provide a controlled release of the drug over an extended period.*

Aim: *This study aims to develop and evaluate sustained-release tablets of Teneligliptin, an anti-diabetic medication, using the liquid solid compact method to enhance its dissolution rate and bioavailability.*

Objective: *The primary objectives of this study are to formulate Teneligliptin SR tablets using the liquid solid technique with excipients such as PEG 400, Tween 80, Xanthan gum, and Tragacanth.To develop an analytical method using UV spectrophotometry for determining the λmax and constructing a calibration curve for Teneligliptin.To evaluate the pre- and post-compression parameters of the formulated tablets, including flow properties, weight variation, thickness, hardness, friability, drug content, and in vitro dissolution. To study the drug release kinetics and ensure the absence of significant drug-excipient interactions using FT-IR spectroscopy.*

Conclusion: *The liquid solid technique proved effective in formulating sustained-release tablets of Teneligliptin, with the tablets exhibiting satisfactory flow properties, compressibility, and uniformity in post-compression parameters. The in vitro dissolution studies indicated that the drug release followed different kinetic models, with formulation F2 showing the best performance, adhering to non-Fickian anomalous diffusion. FT-IR spectroscopy confirmed no significant interactions between the drug and excipients. This study demonstrates the potential of the liquid solid technique in improving the bioavailability and therapeutic efficacy of Teneligliptin in sustained-release formulations.*

Keywords: *Teneligliptin,UV spectrophotometry,FT-IR spectroscopy.*

INTRODUCTION

The liquid solid technique is an innovative approach for enhancing the solubility and bioavailability of poorly water-soluble drugs, especially BCS Class II drugs1, 2 by converting liquid medications into free-flowing, compressible powders using carriers like cellulose and coating materials like fine silica powder, this method significantly improves dissolution rates and drug release profiles. It is simple, cost-effective, and suitable for various water-insoluble drugs, offering benefits over traditional methods such as soft gelatin capsules. Despite challenges in formulating high-dose lipophilic drugs and potential particle agglomeration, the liquid solid technique holds promise for immediate and sustained-release formulations, making it a valuable advancement in drug delivery. Physicochemical properties are crucial for developing optimal drug formulations, understanding biopharmaceutical characteristics, and assessing risks like food effects on bioavailability or drug interactions. Solubility, which is temperature-dependent, influences dissolution rates and, hence, drug absorption, with low solubility limiting absorption and extreme solubility being unsuitable for sustained release products3,4.The partition coefficient (oil/water) is essential for evaluating a drug's ability to penetrate lipid membranes, impacting its formulation into sustained-release dosage forms. Drug stability in the GI tract is

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vital, as solid-state drugs degrade slower, enhancing bioavailability; however, most sustained-release systems release drugs throughout the GI tract. Protein binding, governed by vander Waals forces, hydrogen bonding, and electrostatic forces, can serve as a drug reservoir, with highly bound drugs often having long half-lives, reducing the need for sustained-release forms. Molecular size and diffusivity influence a drug's ability to traverse polymeric membranes in sustained-release systems, with diffusivity being related to the size and shape of both the drug and polymer cavities.

Teneligliptin15is an anti-diabetic drug with the chemical formula C22H30N6OS, 2½ HBr, xH2O and a molecular weight of 628.9 g/mol, is off-white to cream-colored powder, dosed at 20 to 40 mg daily. It inhibits the DPP-4 enzyme, managing glycemic levels without dose adjustments for renally impaired patients, and is well-tolerated, minimizing hypoglycemia and weight gain risks. It is approved in Japan, Argentina, Korea, and India. Magnesium stearate (tablet lubricant, C36H70MgO4, 591.34 g/mol), microcrystalline cellulose (diluent and disintegrant, insoluble in water, improves binding strength), Aerosil20 (docusate sodium, surfactant, C20H37NaO7S, 444.56 g/mol), gum tragacanth (natural gum, emulsifier, thickener, stabilizer), xanthan gum (suspending agent, viscosity-increasing, (C35H49O29)n), Tween 80 (polysorbate 80, emulsifier, C64H124O26, 1310 g/mol), and PEG 400 (polyethylene glycol, hydrophilic, soluble in water and various solvents) are used as a excipients to enhance formulation stability and efficacy.

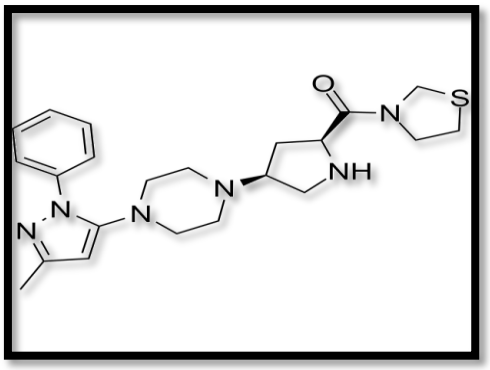

Figure 1: Structure of Teneligliptin

MATERIALS AND METHODS

Materials:

The materials used in the study include Teneligliptin (supplied by Pharma Train), PEG 400, Tween 8017, and Xanthan gum18 (all from Colorcon), Tragacanth16 (FMC Bio Polymer, Mumbai), MCC PH102, Magnesium Stearate19, and Aerosil (all from SD Fine Chemicals, Mumbai). The equipment utilized comprises an electronic weighing balance (Scale-tech), a laboratory oven (DTC-00R), a UV spectrophotometer (Labindia UV 3000+), and a dissolution apparatus (Electro lab TDT-08L).

METHODOLOGY:

I. Analytical Method Development

Preparation of 6.8 phosphate buffer:

Dissolve 27.22g of monobasic potassium phosphate in 1000 ml of water to create a stock solution. Separately, dissolve 8g of sodium hydroxide in 1000 ml of water to obtain a 0.2M sodium hydroxide solution. In a 200-ml volumetric flask, mix 50 ml of the monobasic potassium phosphate stock solution with 22.4 ml of the 0.2M sodium hydroxide solution, then add water to make up the final volume.

Determination of λmax of Teneligliptin 6.8 phosphate buffer:

To prepare the working standard, dissolve 50mg of Teneligliptin in 50ml of 6.8 phosphate buffer, then make up the volume to 50ml with the same buffer to obtain a 1000 µg/ml stock solution. For Dilution 1 and Dilution 2, take 10ml of the stock solution and dilute each to 100ml with 6.8 phosphate buffer to achieve a 10 µg/ml concentration for both. This solutions was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted. The corresponding wavelength having highest absorbance is noted as λmax.=263

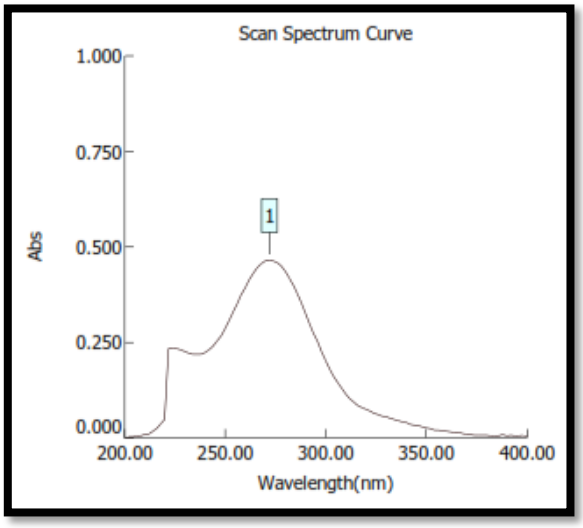

Figure 2: Determination of λmax

Construction of calibration curve of Teneligliptin 6.8 phosphate buffer:

To prepare the working standard, dissolve 50mg of Teneligliptin in 50ml of 6.8 Sodium phosphate buffer and adjust the volume to 50ml with the same buffer to obtain a 1000 µg/ml (ppm) concentrated stock solution. From this stock solution, dilute 10ml with 6.8 phosphate buffer to 100ml to obtain a 100 µg/ml concentrated solution (Dilution 1). From Dilution 1, prepare 2, 4, 6, 8, and 10µg/ml concentrated solutions by taking 0.2, 0.4, 0.6, 0.8, and 1ml respectively, and diluting each to 10ml with 6.8 phosphate buffer. The absorbance of these solutions was measured at λmax=263 nm.

III. Formulation of Teneligliptin SR Tablets by liquid solid compact method

Processing steps involved in liquid solid compact method:

The preparation method for Teneligliptin sustained-release (SR) tablets involved accurately weighing and sieving all ingredients and drug, except Aerosil and magnesium stearate (#60 sieve).

They were mixed with a solvent. The blend was lubricated with magnesium stearate and Aerosil (#40 sieve). Finally, the lubricated blend was compressed into tablets using a 16-station tablet compression machine, using dies ranging from 8mm to 12mm, achieving an average tablet hardness of 4.0 kg/cm^2.

Table1: Formulation of Teneligliptin DR by liquid solid compact method.

Ingredients	Formulation code											
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Teneligliptin	100	100	100	100	100	100	100	100	100	100	100	100
PEG 400	50	50	75	75	100	100						
Tween 80							50	50	75	75	100	100
Xanthum gum	75		75		75		75		75		75	
Traganth		75		75		75		75		75		75
Mcc pH 102	225	225	200	200	175	175	225	225	200	200	175	175
Aerosil	5	5	5	5	5	5	5	5	5	5	5	5
Mg.stearate	5	5	5	5	5	5	5	5	5	5	5	5
Total wt. (mg)	460	460	460	460	460	460	460	460	460	460	460	460

IV. EVALUATION OF TABLETS

The formulated Tablets were evaluated for the following quality control studies & In vitro dissolution studies

Pre formulation studies:

1. Angle of Repose:

The angle of repose is the maximum angle between the surface of a pile of powder and the horizontal plane. It was determined using the funnel method, where a accurately weighed powder blend was placed in a funnel. The funnel height was adjusted so that the tip just touched the apex of the powder blend. The blend was allowed to flow freely through the funnel onto a surface, forming a cone. The angle of repose (q) was calculated using the formula

$$q = \tan^{-1}(h/r)$$

where h is the height and r is the radius of the cone base. This angle is indicative of the flow properties of solids, reflecting inter-particle friction and resistance to movement.

Table 2: Angle of Repose Limits

Flow Properties and Corresponding Angles of Repose

Flow Property	Angle of Repose (degrees)
Excellent	25–30
Good	31–35
Fair—aid not needed	36–40
Passable—may hang up	41–45
Poor—must agitate, vibrate	46–55
Very poor	56–65
Very, very poor	>66

2. Density:

Bulk Density (BD): Measure the mass of powder and its bulk volume without compaction to calculate bulk density using the formula Db = M / V0.

Tapped Density (TD): Measure the mass of powder and its volume after tapping to minimum volume using a tap density tester. Calculate tapped density using Dt = M / Vf.

3. Carr's Index: Calculate compressibility index to assess powder blend compressibility using the formula: Compressibility index (%) = [(Tapped density - Bulk density) / Tapped density] x 100.

4. Hausner's Ratio: Calculate Hausner's Ratio to evaluate powder flowability using the formula: Hausner's Ratio = Tapped density / Bulk density.

Table 3: Compressibility Index Limits

Scale of Flow ability (USP29-NF34)

Compressibility Index (%)	Flow Character	Hausner's Ratio
≤ 10	**Excellent**	**1.00-1.11**
11-15	**Good**	**1.12-1.18**
16-20	**Fair**	**1.19-1.25**
21-25	**Passable**	**1.26-1.34**
26-31	**Poor**	**1.35-1.45**
32-37	**Very Poor**	**1.46-1.59**
> 38	**Very, very Poor**	**> 1.60**

Post compression Parameters:

1. General Appearance: Evaluate tablets for shape, color, texture, and odor.

2. Average Weight/Weight Variation: Weigh 20 tablets collectively and individually to calculate average weight. Check individual weights against average weight limits specified by USP 29-NF 34.

Average weight= weight of 20 tablets/20

$$\% \text{ weight variation} = \frac{(\text{Average weight} - \text{weight of each tablet})}{\text{Average weight}} \times 100$$

Table 4: Weight variation tolerance for uncoated tablets

Acceptance criteria for tablet weight variation (USP 29-NF 34)

Average weight of tablet(mg)	% difference allowed
130 or Less than	± 10
130-324	± 7.5
More than 324	± 5

3. Thickness: Measure tablet thickness using a Vernier caliper (n=3).

4. Hardness Test: Measure tablet hardness using a Monsanto hardness tester (n=3) to assess tablet strength.

5. Friability Test: Determine friability by weighing 20 tablets before and after tumbling in a friabilator. Calculate friability as percentage loss in weight:

$$\% \text{ Friability} = [(W1 - W2) / W1] \times 100.$$

6. Assay Procedure: Analyze drug content of tablets by preparing a solution, diluting, and filtering it. Calculate drug quantity using the formula provided.

$$\% \text{ Assay} = \frac{\text{Test absorbance}}{\text{Standard absorbance}} * \frac{\text{Weight of standard}}{\text{Dilution of standard}} * \frac{\text{Dilution of test}}{\text{Weight of test}} * \frac{\text{Average weight}}{\text{lable claim}} * \frac{\text{\% purity of drug}}{100} * 100$$

7. In vitro Dissolution Study: Conduct dissolution testing using USP-II apparatus (Paddle method) in 6.8 phosphate buffer. Maintain sink conditions, withdraw samples at intervals, and analyze spectrophotometrically at λmax = 263 nm over 12 hours.

Table 5: Dissolution parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	6.8 phosphate buffer
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	1,2,4,6,8,10 and 12hr
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	263 nm

C) In vitro Release Kinetics Studies: Drug release from the sustained-release (SR) tablets was analyzed using different kinetic models to understand the release mechanism:

1. Zero Order Release Kinetics: Describes a constant rate of drug release over time

$$(Q = k0t)$$

where Q is the fraction of drug released at time t and k0 is the zero order release rate constant. A linear plot of drug released versus time indicates zero order kinetics.

2. First Order Release Kinetics: Assumes drug release is proportional to the remaining amount of drug .

$$(\text{Log } C = \text{Log } Co - kt/2.303)$$

where C is the amount of drug dissolved at time t, Co is the initial amount dissolved, and k is the first order rate constant. A linear plot of log cumulative drug remaining versus time suggests first order kinetics.

3. Higuchi Equation: Shows drug release as a square root of time dependence

$$(Q = K2t^{1/2})$$

based on Fick's law of diffusion. A linear plot of drug released versus square root of time indicates Higuchi kinetics.

4. Peppas-Korsemeyer Equation (Power Law): Represents drug release as a power law function

$$(Mt/M\infty = Ktn)$$

where Mt is the amount of drug released at time t, M∞ is the total amount released, K is the kinetic constant, and n is the release exponent. A linear plot of log cumulative drug release versus log time shows the release mechanism governed by Peppas-Korsemeyer equation.

Regression analysis using MS Excel was performed to determine the correlation coefficients and assess the nature of drug release from the tablets according to these kinetic models.

Table 6: Drug release kinetics mechanism

Diffusion exponent(n)	Mechanism
0.45	Fickian diffusion
0.45 < n <0.89	Anomalous(Non-Fickian) diffusion
0.89	Case II transport
n > 0.89	Super Case II transport

RESULTS AND DISCUSSION

Construction of Standard calibration curve of Teneligliptin in 6.8 phosphate buffer:

The absorbance of the solution was measured at 243nm, using UV spectrometer with 6.8 phosphate buffer as blank. The values are shown in table . A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer's law in the concentration range 2 to 10 µg/ml.

Table 7: Standard Calibration graph values of Teneligliptin in 6.8 phosphate buffer

Concentration (µg / ml)	Absorbance
0	**0**
2	**0.128**
4	**0.253**
6	**0.387**
8	**0.509**
10	**0.645**

Standard plot of Teneligliptin plotted by taking absorbance on Y – axis and concentration (µg/ml) on X – axis, the plot is shown in fig.

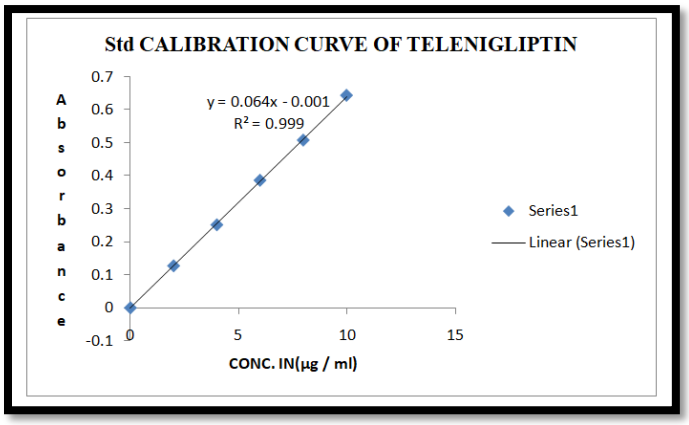

Fig 3: Standard calibration curve of Teneligliptin in 6.8 phosphate buffer

Inference: The standard calibration curve of Teneligliptin in 6.8 phosphate buffer showed good correlation with regression value of 0.9993

Evaluation of Tablets:

Table 8: Pre formulation studies of Teneligliptin SR Tablets

Formulation Code	Bulk density (Kg/cm3)	Tapped density (Kg/cm3)	Cars index	Hausners ratio	Angle of repose
F1	0.43	0.52	17.3	1.41	12.62
F2	0.40	0.46	13.0	1.5	12.29
F3	0.50	0.58	13	1.16	11.58
F4	0.44	0.51	13.7	1.25	9.29
F5	0.39	0.47	17.0	1.56	18.23
F6	0.42	0.52	19.2	1.45	13.24
F7	0.36	0.39	7.6	1.0	11.03
F8	0.41	0.50	18	1.5	17.4
F9	0.39	0.48	18	1.23	11.96
F10	0.41	0.51	19.6	1.53	12.26
F11	0.44	0.52	15.3	1.40	13.62
F12	0.41	0.45	8.8	1.0	11.85

Inference:

- Teneligliptin SR Tablets were evaluated for flow properties, as detailed in Table 8.
- Bulk density and tapped density across all formulations were consistent.
- Carr's index and Hausner's ratio ranged from ≤ 18 and 1.0 to 1.56, respectively, indicating good flow and compressibility of the blends.
- Angle of repose for all formulations ranged from 11.03° to 18.23°, suggesting passable flow; incorporation of a glidant could further enhance flow properties.

Table 9: Post formulation studies of Teneligliptin SR Tablets

Formulation Code	% weight vaiation	Thickness (mm)	% friability	% Drug Content	Hardness (Kg/cm2)
F1	pass	3.66±0.11	0.22	102.0 ±1.1	6.68 ±0.17
F2	pass	3.93±0.15	0.15	101.3 ±1.5	6.13 ±0.15
F3	pass	4.06±0.057	0.12	99.8±1.3	6.58 ±0.13
F4	pass	4.81±0.1	0.43	101.7 ±0.8	6.98 ±0.04
F5	pass	4.03±0.05	0.32	100.6±1.2	6.63 ±0.05
F6	pass	3.83±0.15	0.14	98.9 ±2.1	6.2 ±0.02
F7	pass	4.93±0.05	0.20	99.2± 1.7	6.7 ±0.10
F8	pass	5.26±0.1	0.33	99.5± 1.4	6.93 ±0.05
F9	pass	4.02±0.2	0.18	99.2±1.3	6.39 ±0.02
F10	pass	4.48±0.14	0.21	100.3 ±1.4	6.86 ±0.03
F11	pass	4.91±0.18	0.32	101.2± 1.6	6.72 ±0.12
F12	pass	5.14±0.12	0.16	100.3 ±1.8	5.89 ±0.13

Inference:

- The variation in weight was within the limit
- The thickness of tablets was found to be between 3.66 - 5.26 mm.
- The hardness for different formulations was found to be between 5.89 to 6.98 kg/cm2, indicating satisfactory mechanical strength
- The friability was < 1.0% W/W for all the formulations, which is an indication of good mechanical resistance of the tablet.
- The drug content was found to be within limits 98 to 102 %.

INVITRO DISSOLUTION STUDIES OF TENELIGLIPTIN SR TABLETS:

Table10: Dissolution profile

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	6.8 phosphate buffer
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	1,2,4,6,8,10 and 12hr
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	263 nm

Note: 5 ml of sample was with draw at each time point & replace the same volume of 6.8 phosphate buffer preheated to 37± 0.5 ºC

Table11: In-vitro Dissolution results of Formulation trails

Time (Hrs)	% DRUG RELEASED											
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0	0	0	0	0	0	0
1	39	16	33	14	16	13	32	38	28	35	25	31
2	50	26	49	21	29	24	45	65	41	61	39	55
4	69	41	58	37	40	36	69	84	64	79	60	69
6	81	62	67	59	50	48	81	100	77	96	76	81
8	96	81	75	68	67	59	94		87	100	84	93
10	100	94	86	77	78	69	100		100		100	100
12		100	93	89	84	81						

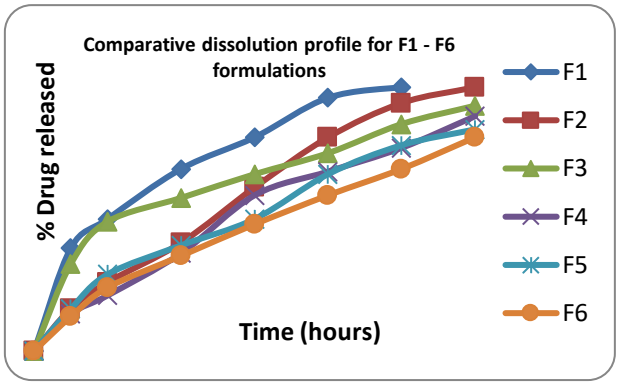

Fig 4: Comparative dissolution profile for F1-F6 formulations

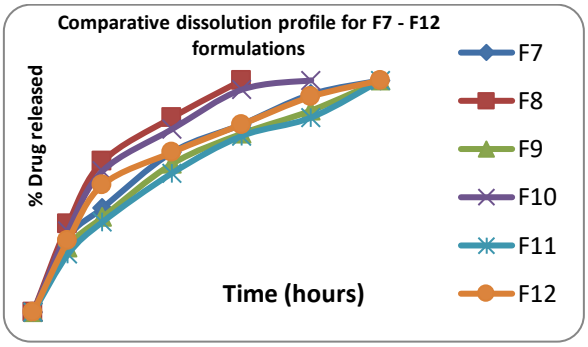

Fig 5: Comparative dissolution profile for F7-F8 formulations

Table12: R2 value and n result table

Formulation Code	R2 value				n value
	Zeroorder	Firstorder	Higuchiplot	Peppasplot	
F1	0.875	0.932	0.992	0.995	0.424
F2	0.980	0.879	0.962	0.994	0.767
F3	0.863	0.94	0.984	0.98	0.385
F4	0.977	0.986	0.965	0.99	0.778
F5	0.969	0.975	0.979	0.988	0.657
F6	0.982	0.996	0.975	0.995	0.707
F7	0.907	0.992	0.996	0.995	0.532
F8	0.882	0.993	0.991	0.967	0.526
F9	0.928	0.994	0.997	0.997	0.575
F10	0.854	0.987	0.982	0.968	0.546
F11	0.943	0.994	0.993	0.999	0.621
F12	0.869	0.961	0.988	0.949	0.519

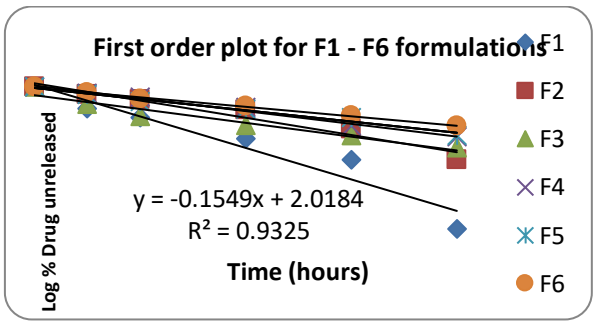

Fig 6: First order plot for F1 - F6 formulations

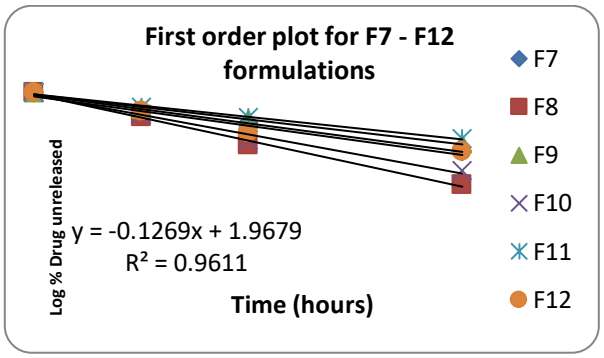

Fig 7: First order plot for F7 – F12 formulations

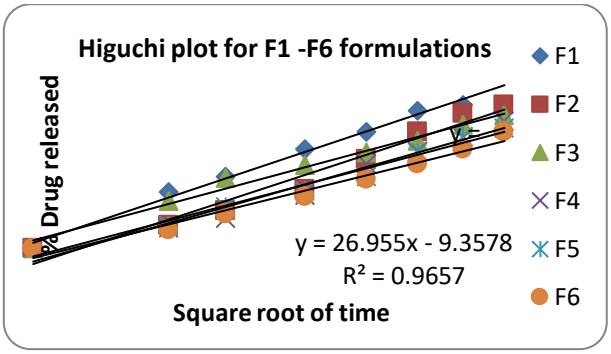

Fig 8: Higuchi plot for F1 – F6 formulations

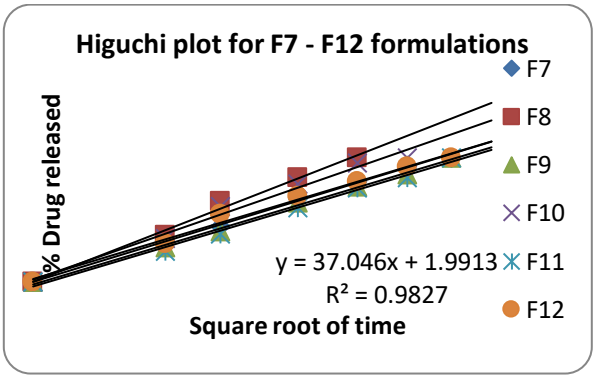

Fig 9: Higuchi plot for F7 – F12 formulations

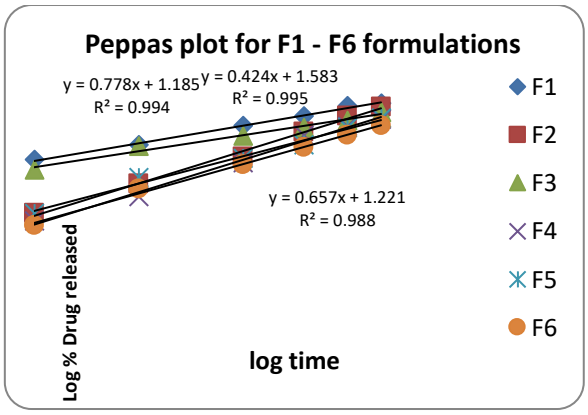

Fig 10: Korsmayerspepas plot for F1-F6 formulations

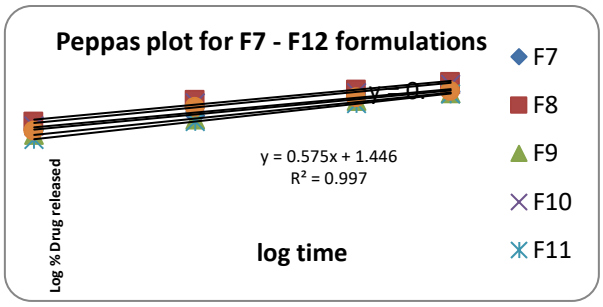

Fig 11: Korsmayerspepasplot for F7-F12 formulations

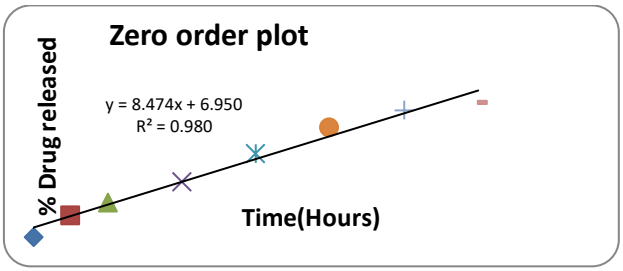

Figure 12: Zero order plot for F2 formulation

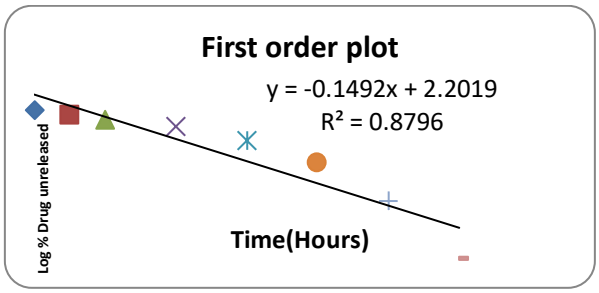

Figure 13: First order plot for F2 formulation

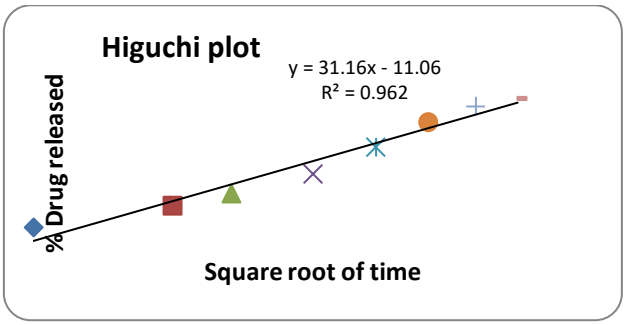

Figure 14: Higuchi plot for F2 formulation

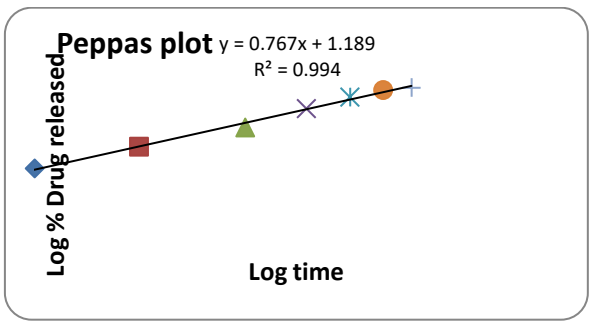

Figure 15: Peppas plot for F2 formulation

Inference

- Among all formulations F2was showing the satisfactory results.
- For the F2 formulation diffusion exponent n value is in between 0.45 to 0.89 so they are following nonfickiananmolous diffusion model

FT-IR spectroscopy

The FTIR spectra, observed that the characteristic absorption peaks of pure Teneligliptin were obtained at 3087.56, 2994.16, 1707.56, 1460.7, 13620.10 and 705.5cm-1 corresponding to O-H, C-H, C=O C-C, C-O stretching and OH- bending (Figure1). The spectral data suggests that the major peaks for drugs are obtained as nearer value and there were no considerable changes in IR peaks in all physical mixtures of drug and polymers. This indicates that the drugs were molecularly dispersed in the polymers or in drug loaded formulations thus thereby indicating the absence of any interactions.

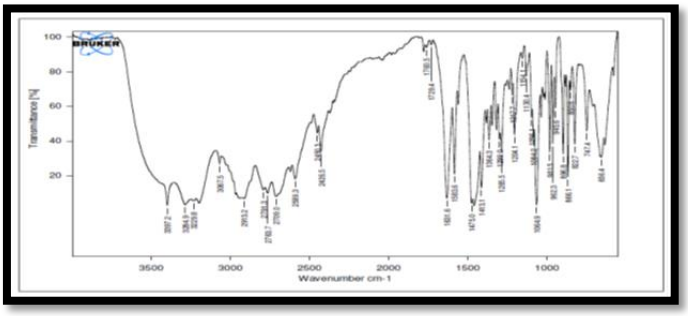

Fig 16: FTIR graph for Teneligliptin pure drug

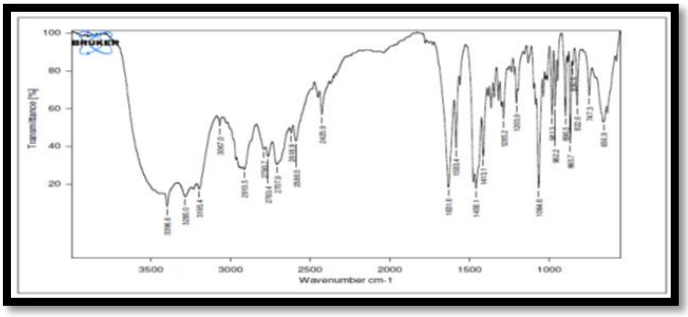

Fig 17: FTIR graph for formulation F2

SUMMARY AND CONCLUSION

This study aimed to compare Xanthan gum and Tragacanth polymers and evaluate how the physico-chemical properties of active ingredients influence drug release profiles using the liquid solid compact method with PEG400 and Tween 80. The formulations exhibited suitable characteristics for this compaction method based on angle of repose, compressibility index, and sieve analysis results. The research demonstrated the potential of Teneligliptin for sustained release formulations, offering prolonged therapeutic action within safe dosage limits compared to conventional forms, thereby potentially reducing dosing frequency and enhancing patient compliance. The drug

release kinetics followed first-order kinetics, and the release mechanism from sustained release tablets aligned with the Higuchi model. Successful in vitro release results suggest the formulation's suitability for further in vivo studies, promising improved clinical outcomes and patient adherence.

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